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Section II

510(k) SUMMARY

General Information Required for Premarket Notification per 21 CFR 807.87

510k Number: K053411	
Submitter:	Microgenics Corporation 46360 Fremont Blvd Fremont, CA 94538 Telephone: (510)-979-5000 Facsimile: (510) 979-5255
Contact Person:	Tony C. Lam Telephone: (510)-979-5055 Facsimile: (510) 979-5255 tlam@microgenics.com
Device's Trade Name:	DRI® Hemoglobin A1c Assay
Device's Classification Name:	Glycosylated Hemoglobin Assay
Registration Number:	2937369 (Microgenics Corp. Fremont, CA, US)
Regulation Number:	21 CFR 864.7470
Classification:	Class II
Product Code:	LCP

Predicate Device(s):

Tosoh G7 Automated High Performance Liquid Chromatography (HPLC) Analyzer: HbA1c Variant Analysis Mode.

Device Description:

DRI® Hemoglobin A1c Assay, including calibrators, is a homogeneous immunoassay that measures HbA1c in human whole blood using automated clinical chemistry analyzers. The assay is based on the measurement of light scattering from the agglutination of microparticles. Hemoglobin and HbA1c in samples bind to microparticles by adsorption nonspecifically at the same rate. When HbA1c specific antibody is introduced, the antibody binds to HbA1c on the microparticles resulting in agglutination. The extent of agglutination is directly proportional to the percentage of HbA1c present in the total hemoglobin and can be monitored spectrophotometrically. This technology used in the DRI hemoglobin A1c assay is an established method (ref 1).

DRI Hemoglobin A1c Assay kit contains reagent 1, 2a, 2b and a hemolysis buffer. All are in liquid format.

DRI Hemoglobin A1c Calibrator kit contains four lyophilized positive calibrators with different hemoglobin A1c concentrations and one saline solution that serves as negative hemoglobin calibrator.

Intended Use:

The DRI® Hemoglobin A1c Assay is an in vitro reagent system for the quantitative determination of Hemoglobin A1c in human whole blood using automated clinical chemistry analyzers. It is intended to aid in monitoring long-term blood glucose control in individuals with diabetes mellitus.

The DRI® Hemoglobin A1c Calibrators are intended for use in the calibration of the DRI® Hemoglobin A1c Assay in human whole blood.

DRI® Hemoglobin A1c Assay comparison to Predicate Device(s):

The DRI® Hemoglobin A1c Assay, including calibrators, is substantially equivalent to Tosoh G7 HPLC Analyzer in its intended use and in for the quantitative determination of HbA1c concentration in whole blood sample.

Device Characteristics	**Subject Device** (DRI HbA1C Assay)	**Predicate Device** (Tosoh G7 Automated HPLC Analyzer: HbA1c Variant Analysis Mode)
Intended Use	The DRI® Hemoglobin A1c Assay is an in vitro reagent system for the quantitative determination of Hemoglobin A1c in human whole blood using automated clinical chemistry analyzers. It is intended to aid in monitoring long-term blood glucose control and compliance in individuals with diabetes mellitus. The DRI® Hemoglobin A1c Calibrators are intended for use in the calibration of the DRI® Hemoglobin A1c Assay in human whole blood.	The Tosoh G7 automated HPLC Analyzer-HbA1c Variant Analysis mode is intended for *in vitro* diagnostic use for the measurement of hemoglobin A1c (HbA1c) in whole blood specimens. Hemoglobin A1c measurements are used in the clinical management of diabetes to assess the long-term efficacy of diabetic control.
Analyte	Hemoglobin A1c	Hemoglobin A1c and total Hemoglobin A
Matrix	Whole blood	Whole blood
Calibrator Level	5 levels calibrators including a negative	2 points

Summary:

The information provided in this pre-market notification demonstrates that the DRI® Hemoglobin A1c Assay including calibrators is substantially equivalent to Tosoh G7 Automated HPLC Analyzer. Tosoh G7 Automated HPLC Analyzer is certified by the National Glycohemoglobin Standardization Program (NGSP). It is used as a reference method for establishing traceable results of other methods to the Diabetes Control and Complications Trial (DCCT). Data and results provided in this premarket notification were collected and prepared, respectively, in accordance with the NGSP and NCCLS guidance. The performance of the DRI Hemoglobin A1c Assay including calibrators is substantially equivalent to Tosoh G7 Automated HPLC Analyzer for the quantitative determination of HbA1c, as approved by NGSP manufacturer certification (see attached NGSP certification).

The performance of the assay were conducted using DRI Hemoglobin A1c Assay kit and calibrator kit are summarized below:

Performance	Results	
Limit of Detection	0.2%	
Precision (n=80)	**Normal HbA1c Sample**	**Elevated HbA1c Sample**
Within run	0.67%CV	0.62% CV
Total run	2.03% CV	2.36%CV
Assay Linearity	**5.2% to 16% HbA1c concentration**	
Interference	**No interference observed with**	
	Billirubin	50 mg/dL
	Ascorbic Acid	50 mg/dL
	Triglycerides	1000 mg/dL
	EDTA	6 mg/mL
	Heparin	75 units/mL
	Citrate	9 mg/mL
	Oxalate	15 mg/mL
Method Comparison DRI HbA1c vs Tosoh (n=80)	**Deming (95% CI)**	**Regular (95%CI)**
Slope	0.999 (0.969 to 1.028)	0.995 (0.965 to 1.024)
Intercept	0.176 (-0.067 to 0.419)	0.210 (-0.033 to 0.453)
Std Err Est	0.254	0.254
Correlation	0.9915	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Tony C. Lam, MS
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Microgenics Corporation
46360 Fremont Blvd.
Fremont, CA 94538

FEB 3 2006

Re: k053411
Trade/Device Name: DRI® Hemoglobin A1c Assay
DRI® Hemoglobin A1c Calibrators
Regulation Number: 21 CFR § 864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: Class II
Product Code: LCP, KRZ
Dated: November 30, 2005
Received: December 7, 2005

Dear Mr. Lam:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

SECTION III

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K053411

Device name: DRI® Hemoglobin A1c Assay
DRI® Hemoglobin A1c Calibrators

Indications for Use:

The DRI® Hemoglobin A1c Assay is an in vitro reagent system for the quantitative determination of Hemoglobin A1c in human whole blood using automated clinical chemistry analyzers. It is intended to aid in monitoring long-term blood glucose control in individuals with diabetes mellitus.
The DRI® Hemoglobin A1c Calibrators are intended for use in the calibration of the DRI® Hemoglobin A1c Assay in human whole blood.

Prescription Use __X_____ AND/OR Over-the Counter Use_____
(Part 21 CFR §801 Subpart D) (21 CFR §807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Ann Chappie
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K053411